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10/535,198	03/31/2006	Nardino Righi	2504-1163	5636

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,198	RIGHI ET AL.	
	Examiner	Art Unit	
	VICTORIA P. CAMPBELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-14 and 16-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-14 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the second Office Action based on the 10/535198 application filed March 31, 2006, which is a 371 national stage entry of PCT/IT02/00730, filed November 18, 2002. Claims 1-5, 8-14, and 16-19 as amended are currently pending and considered below.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-5, 8-14, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,376,080 to Petrussa in view of USPGPub 2001/0037089 to Domici, Jr. and USPN 4,737,144 to Choksi.

Regarding claims 1-5, 9-14, 16, and 19, Petrussa discloses the following:

With respect to claim 1, Petrussa teaches

> a guard mechanism attachable to a syringe to make it into a disposable automatic safety syringe, said syringe comprising: a syringe body (Fig. 1, #14) hollow on the inside and open at the front and rear, a plunger (Col. 3, lines 57-58, notes a normal seal-engagement packing) sliding inside the syringe body with an injection stroke extending from a retracted syringe-filling position to a forward syringe-emptying position, said plunger being provided at the rear with a shaft (Fig. 1, #15) that can be operated manually and brought out of the syringe body by means of the rear end (Fig. 1, not labeled) thereof, and an injection needle (Fig. 1, #11) incorporated into a needle-carrier (Fig. 1, #16) engageable in the head of the syringe body (Fig. 1, not labeled), wherein said guard mechanism is arranged and adapted to be pre-assembled and comprises: a sleeve (Fig.1, #20) that can be slidably mounted on said syringe body, a spring (Fig. 1, #12) housed in said sleeve, and a abutment member (Fig. 1, #18) for said spring, also housed in said sleeve and able to be made integral with the front part of said syringe body.

Regarding claim 2, Petrussa teaches

> a mechanism according to claim 1, wherein in said pre-assembled condition, said abutment member (Fig. 1, #18) for said spring (Fig. 1, #12) is retained by said pair of rear tongues (Fig. 1, #24) protruding inward from said sleeve (Fig. 1, #20), said pair of rear tongues being flexible.

With regards to claim 3, Petrussa teaches

> The mechanism according to claim 1, wherein during operation said sleeve (Fig. 1, #20) is slidably mounted on said syringe body (Col. 3, lines 61-66), to pass from a retracted position of use of the syringe, to a forward position of safety, wherein it covers said needle (Col. 2, lines 40-51), and said spring is disposed under compression in the front part of said sleeve, between said sleeve and said abutment member made integral with said syringe body (Fig. 1, spring [#12] is compressed between the front of the sleeve [#27] and the abutment ring [#18]), to urge the axial movement of the sleeve with respect to the syringe body, the mechanism further comprising: locking means disposed in the rear part of the sleeve (Fig. 4, #24) and in the rear part of the syringe body (Fig. 4, #25) in reciprocal engagement, to keep the sleeve locked in the retracted position of use against the action of said spring, and operating means disposed in said shaft (Fig. 4, #25) to release said locking means, when the plunger reaches the end of the injection stroke, so as to allow the axial movement of the sleeve into the safety position, thanks to the action of said spring.

With regards to claim 4, Petrussa shows the following

> The mechanism according to claim 1, wherein said abutment member comprises: a cylindrical or frusto-conical body (Fig. 5a, #18), hollow on the inside to be applied to the front part of the syringe body, e a cylindrical or frusto-conical tang (Fig. 5a, unlabeled, but pictured as part of the retention element [#35]) with a smaller diameter than the body and protruding forward therefrom so as to give rise to a shoulder (Fig. 5a, unlabeled).

With regards to claim 5, Petrussa teaches the following

> a mechanism according to claim 4, wherein said spring is a spiral spring (Fig. 6b, #12) disposed in the front part of the sleeve (Fig. 1, spring #12 is shown in compressed conformation), around the tang (Fig. 1, #35) of the abutment member, with one end of the spring abutting against a collar (Fig. 1, #27) protruding inward in the front edge of the front part of the sleeve and the other end of the spring abutting against the shoulder (Fig. 1, unlabeled) of the abutment member.

Regarding claim 9, Petrussa teaches the following

> a mechanism according to claim 1 wherein said other locking means for locking the sleeve in the retracted position of use comprise a collar (Fig. 1, #25) protruding radially outward from the rear edge of the syringe body (Fig. 1, #14) able to abut against said rear tongues (Fig. 1, #24) formed in the rear part of the sleeve (5), said rear tongues being flexible and ending in respective abutment

surfaces (Fig. 1, not labeled) able to abut against said collar to retain the syringe body (see Fig. 4 for more detailed drawing of locking means).

With regards to claim 10, Petrussa teaches

a mechanism according to claim 9, wherein said flexible rear tongues (Fig. 4, #24) are inclined slightly inward to cooperate with a circular operating crown (Fig. 4, #26), when the plunger is at the end of the injection stroke.

With respect to claim 11, Petrussa teaches the following

a mechanism according to claim 1, wherein said sleeve has outwardly protruding gripping means, to give rise to a resting surface for the user's fingers (Fig. 1, not labeled. The outer flange of the sleeve that contains the teeth [#24] is usable as a gripping means for the user's fingers).

With respect to claim 12, Petrussa teaches

a disposable automatic safety syringe comprising: a syringe body (Fig. 1, #14) hollow on the inside and open at the front and rear, a plunger (Col. 3, lines 57-58, notes a normal seal-engagement packing) sliding in the syringe body with an injection stroke extending from a retracted syringe-filling position to a forward syringe-emptying position, said plunger being provided at the rear with a shaft (Fig. 1, #15) that can be operated manually and brought out of the syringe body by means of the rear end (Fig. 1, not labeled) thereof, an injection needle (Fig. 1, #11) supported by a needle-carrier (Fig. 1, #16) engageable to the front end (Fig. 1, #27) of the syringe body, a sleeve (Fig. 1, #20) slidably mounted over said

syringe body, to pass from a retracted position of use of the syringe wherein the needle protrudes forward therefrom, to a forward position of safety, wherein it covers said needle, an abutment member (Fig. 1, #18) able to be made integral with the front part of the syringe body, spring means (Fig. 1, #12) disposed under compression in the front part of said sleeve, between said sleeve and said abutment member to urge the axial movement of the sleeve with respect to the syringe body, first locking means (Fig. 1, #24, #25) provided in the rear part of the sleeve and in the rear part of the syringe body, in reciprocal engagement, to keep the sleeve locked in the retracted position of use against the action of said spring means, and operating means (Fig. 1, #26) disposed in said shaft to disengage said locking means, when the plunger reaches the end of the injection stroke, so as to allow axial movement of the sleeve into the safety position, thanks to the action of said spring means.

With regards to claim 13, Petrussa teaches the following

a syringe according to claim 12, wherein said abutment member comprises: a cylindrical or frusto-conical body (Fig. 5a, #18), hollow on the inside to be applied to the front part of the syringe body, and a cylindrical or frusto-conical tang (Fig. 5a, unlabeled, but pictured as part of the retention element) with a smaller diameter than that of the body and protruding forward therefrom so as to give rise to a shoulder (Fig. 5a, unlabeled).

Regarding claim 14, Petrussa teaches

a syringe according to claim 13, wherein said spring means comprise a spiral spring (Fig. 6b, #12) disposed inside the front part of the sleeve (Fig. 1, spring #12 is shown in compressed conformation), around the tang (Fig. 1, #35) of the abutment member, with one end of the spring abutting against a collar (Fig. 1, #27) protruding inward in the front edge of the front part of the sleeve and the other end of the spring abutting against the shoulder of the abutment member (Fig. 1, unlabeled).

Regarding Claim 16, Petrussa teaches the following

wherein said locking means for locking the sleeve in the retracted position of use comprise a collar (Fig. 1, #25) protruding radially outward form the rear edge of the syringe body (Fig. 1, #14) and able to abut against the pair of flexible rear tongues (Fig. 1, #24) formed in the rear part of the sleeve. (See Fig. 4 for more detailed drawing of locking means).

With respect to claim 19, Petrussa teaches

A hollow syringe body (Fig. 1, #14) open at front and rear ends; a plunger slidable in the syringe body, a rear of said plunger including a shaft that is removable from the rear end of the syringe body (Col. 3, lines 57-58; Fig. 1, #15); an injection needle carrier engageable to the front end of the syringe body (Fig. 1, #16); a sleeve slidably mounted over said syringe body (Fig. 1, #20), said sleeve being movable from a retracted position of syringe use when the needle protrudes forward of the syringe, to a forward position of safety where the sleeve

covers said needle; an abutment member at a front part of the syringe body (Fig. 1, #18); a compression spring in the front part of said sleeve between said sleeve and said abutment member (Fig. 1, #12); a locking member provided in the rear part of the sleeve that cooperates with a rear part of the syringe body to keep the sleeve locked in the retracted position (Fig. 4, #24); an operating element connected to the shaft to disengage said locking member when the plunger reaches an end of an injection stroke (Fig. 4, #25) [...].

Regarding claims 1, 12, and 19, Petrussa fails to explicitly teach or disclose a pair of front and a pair of rear tongues formed in the sleeve, with respective abutment members, which abut against the shoulder and rear surface of the abutment member in order to lock the sleeve into place.

Regarding the above claims, Domici, Jr. teaches locking means (Fig. 1, #16, 20) that lock the sleeve (Fig. 1, #40) in a forward position, comprising a pair of front tongues (Fig. 1, #16) and a pair of rear tongues (Fig. 1, #20) having respective abutment surfaces (Fig. 1, #24, 28) to abut against the shoulder (Fig. 2, #64) and rear edge (Fig. 2, #62) of the abutment member, respectively.

Domici, Jr. does not teach, however, that the tongues are formed on the sleeve of the device. Instead, in the device described by Domici, Jr., the tongues are on the syringe body itself. Choksi teaches a single locking means (Fig. 1, #20) on the sleeve itself. Modifying the locking means of Domici, Jr. by moving them to the sleeve of the device from the syringe body as in Choksi is an obvious variant that yields predictable

results. Petrussa, Domici, Jr., and Choksi all teach equivalent methods of locking a sliding needle guard in place in an extended position, shielding the needle of a syringe. Because Petrussa, Domici, Jr., and Choksi, all teach equivalent elements to perform the same task, modifying the locking mechanism of Petrussa with the combined teachings of Domici, Jr. and Choksi would have been obvious to one of ordinary skill in the art.

With regard to claim 8, Choksi also teaches

> a mechanism according to claim 7, wherein said pairs of opposed tongues of the sleeve (Fig. 1, #20) are flexible and are formed by means of substantially U-shaped opposed cuts (Fig, 1, not labeled) in the sleeve body, to be able to bend radially inward and outward with respect to the sleeve (Fig. 8).

5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petrussa, Domici, Jr., and Choksi in further view of USPN 7,118,552 to Shaw et al.

Regarding claim 17, Petrussa in combination with Domici, Jr and Choksi teach the limitations of claim 12 as described above, but they fail to teach the presence of a safety tab. Shaw et al teach the following:

> wherein in the rear part of said shaft (Fig. 4, #450) of the plunger (Fig. 4, #450) there is provided a safety tab (Fig. 4, #470) removable by the user (Col. 12, line 54) and able to abut against the rear edge of the sleeve to prevent the plunger from reaching the end of the injection stroke (Col. 6, lines 11-16).

The plunger of Petrussa, Domici Jr. and Choksi could be compressed fully at any time, releasing the shield at a time when the operator did not intend (i.e. before or

during use). Shaw et al teach a safety tab attached to the plunger of a syringe to prevent full movement of the plunger because full movement of the plunger engages the retraction mechanism, as does full movement of the plunger in the present invention. Thus, it would have been obvious to one of ordinary skill in the art of syringes to add the removable safety tab of Shaw et al to the syringe of Petrussa in order to prevent the user from retracting the syringe into the sleeve before the operator was prepared for disposal.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petrussa, Domici Jr, and Choksi as applied to claim13 above, and further in view of USPN 6,419,658 B1 to Restelli et al.

Petrussa, Domici Jr, and Choksi teach the device of claim 13 as described above, but fail to teach or disclose that the tang of the abutment member is shaped as a Luer cone. However, Restelli et al teach the following:

> wherein said tang (Fig. 4, #18) of the contrast element (Fig. 4) is shaped on the inside as a Luer cone to support the needle-carrier (Fig. 4, #22).

Examiner notes that Luer fittings are commonly used for syringe connections and would make the syringe compatible with pre-existing needles. The widespread use of Luer fittings, including Luer cones, would have made their use in this particular invention obvious to one of ordinary skill in the art.

Response to Arguments

7. Applicant's arguments filed January 17, 2008 have been fully considered but they are not persuasive.

8. In light of the amendments to the claims and specification, the examiner hereby withdraws any previous objections to the drawing, specification, and claims.

9. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

10. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

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